EXHIBIT 7

(Original Exhibit No. 165-14)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	**Lead Case No. 3:21-cv-03825-VC**
THIS DOCUMENT RELATES TO: **All Actions**	

SUPPLEMENTAL EXPERT REPORT OF KIMBERLY A. TRAUTMAN, M.S.

March 1, 2023

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I. INTRODUCTION

1. In her expert report (hereinafter "Foreman Report"), Christy Foreman stakes out the extreme position that it is clearly and absolutely unlawful for independent repair companies ("IRCs") to service,[1] refurbish,[2] or reprocess[3] Intuitive's EndoWrist medical devices absent 510(k) clearance from the U.S. Food and Drug Administration ("FDA").[4] But she points to no binding FDA regulation or official statement endorsing that position—which is unsurprising, because there is none.

2. Instead, as discussed in my original report and here below, FDA still has not articulated in any formal regulation, policy document, or guidance document what—if any—FDA obligations third parties or IRCs might have when performing servicing, refurbishing, or reprocessing activities on reusable medical devices. FDA thus has effectively decided that such

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[1] "Service: Repair and/or preventive or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that significantly change the finished device's safety or performance specifications, or intended use." *See* the FDA draft guidance, *Remanufacturing of Medical Devices*, (June 2021) at https://www.fda.gov/media/150141/download.

2 "Recondition/Refurbish/Rebuild: Restores a medical device to the OEM's original specifications or to be "like new." The device may be brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications, or intended use. These activities include repair of components, installation of OEM provided updates and upgrades, and replacement of worn parts." *See* the FDA draft guidance, *Remanufacturing of Medical Devices*, (June 2021) at https://www.fda.gov/media/150141/download.

3 "Reprocessing: With respect to reusable devices, means validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use on a patient. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization." *See* the FDA guidance, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, (Mar. 2015), at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

[4] Expert Report of Christy Foreman, *In re: Da Vinci Surgical Robot Antitrust Litig.*, No. 3:21-cv-03825-VC (Jan. 18, 2023), at ¶ 198 ("What the third parties do is in fact remanufacturing. There is no ambiguity on this point.")

entities should *not* be regulated as 1) "remanufacturers"[5] that 2) do not intend to "introduc[e] [medical devices] into interstate commerce for commercial distribution,"[6] the two necessary prerequisites for 510(k) clearance to be required. FDA has promised third parties and IRCs that regulatory expectations would be announced as far back as the Advance Notice of Proposed Rule Making in 1998, and yet, to date, FDA still has not resolved or finalized its position to clearly distinguish what is considered "servicing" versus "remanufacturing" for reusable medical devices.

3. The reality is that, contrary to Foreman's absolute, extreme, and incorrect position, FDA's longstanding refusal to either (a) subject third parties performing serving activities to the same regulatory requirements as remanufacturers, or (b) clarify the line between them in a way that clearly pulls additional activities under the "remanufacturing" umbrella, has left open two other possibilities regarding IRCs performing servicing functions: (1) FDA-related regulations, including 510(k) clearance, clearly are *not* required due to FDA in 1997 revoking the 1987 Reconditioner/Rebuilder FDA Compliance Policy Guide (CPG) 7124.28;[7] or (2) the issue is unresolved. If the correct position is ***either*** of these two possibilities—and I show in my opening report and below that these are the only two correct possibilities—then IRCs would be

[5] *See* 21 CFR § 820.3(w) (defining "remanufacturer").
[6] *See* 21 CFR § 807.81 ("When a premarket notification submission is required"); *see also* 21 CFR § 807.3(b) ("Commercial distribution means any distribution of a device intended for human use which is held or offered for sale.").
[7] In 1998, FDA revoked CPG 7124.28, which pertained to "reconditioners/rebuilders," as it overlapped with, and was inconsistent with, the 1996 Quality System regulation rulemaking. The 1987 FDA CPG 7124.28 had previously stated that reconditioners and rebuilders of medical devices were subject to requirements for establishment registration, premarket notification, labeling, FDA inspection, good manufacturing practices, and medical device reporting. The CPG identified a "reconditioner/rebuilder" as a person or firm that acquires ownership of a used device and, for purposes of resale or commercial distribution, "restores" or "refurbishes" the device to the manufacturer's original or current specifications or new specifications. *See* 63 Fed. Reg. 67076.

expected, by both FDA and other market participants, to continue their servicing, refurbishing, or reprocessing activities unless and until FDA clarifies their regulatory obligations or raises specific concerns regarding a particular IRC's practices.

II. BACKGROUND

4. On December 1, 2022, I submitted an expert report in this litigation opining on issues related to FDA regulatory requirements under Section 510(k) of the Federal Food, Drug, & Cosmetic Act ("FDCA") and related FDA regulations.[8] I am now supplementing my opinions through this reply report. I am also supplementing the list of materials I considered in forming my expert opinion (attached as Appendix A).

5. FDA's Center for Devices and Radiological Health ("CDRH") is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States. FDA-regulated products at issue here are Intuitive's "da Vinci Surgical System," which is a Class II surgical robot, and its associated EndoWrist instruments, used in minimally invasive surgical procedures. As discussed in my original report, third-party IRCs have repaired, serviced, reprocessed, and refurbished similar reusable medical devices from a variety of medical device manufacturers.

6. At the request of the purchasers and users (generally hospitals) of the da Vinci robot, IRCs were contracted to and performed repair and servicing activities on EndoWrist reusable instruments to extend their use. Most of the activities performed by these IRCs were standard repair and servicing functions, such as sharpening, tightening, etc., by agreement with the instrument's hospital owners. However, since Intuitive technologically restricted the number

[8] Expert Report of Kimberly A. Trautman, *In re: Da Vinci Surgical Robot Antitrust Litigation*, No. 3:21-cv-03825-VC (Dec. 1, 2022) (hereinafter "Trautman Opening Report").

of uses of the instruments via the use counter, these IRCs also had to "reset" the use counters to allow the reusable instruments to continue to be used with the hospital's da Vinci robot.

III. SUMMARY OF OPINIONS

7. FDA has decided not to subject reusable medical device IRCs to the 510(k) clearance requirement unless those companies *both* a) satisfy the regulatory definition of "remanufacturer," *and* b) place the medical devices at issue in "commercial distribution." As stated in my original report,[9] FDA has elected to permit IRCs to operate in this space against the backdrop of an ongoing lack of clarity regarding whether specific servicing activities meet any regulatory definition or impose regulatory obligations. To date, FDA still has not issued the promised rulemaking from the December 4, 1998 (63 FR 67076)[10] Advance Notice of Proposed Rulemaking. Nor has FDA finalized policies in a guidance document to represent the agency's current thinking (per FDA's Good Guidance Practices[11]) on: a) clarity around servicing vs. remanufacturing activities related to the definition of "remanufacturer;" and b) the applicability of any regulatory requirements for third parties that service and/or refurbish medical devices but do not place those devices into interstate commerce for commercial distribution.

8. Because FDA's long-promised rulemaking still has not been promulgated, IRCs or third-party servicers and refurbishers who do not place medical devices into interstate commerce for commercial distribution have not been subject to FDA regulations since at least 1997. I believe that, based on FDA's approach in this area, FDA would not require 510(k) clearance for an IRC (that is not a reseller) to extend the lives of EndoWrist instruments, nor

[9] Trautman Opening Report, at ¶¶ 10, 48, 49, 83.
[10] 63 Fed. Reg. 67076 (Dec. 4, 1998).
[11] 62 Fed. Reg. 8961 (Feb. 27, 1997).

would FDA require compliance with the Quality System regulation 21 CFR § 820 or other FDA regulations, such as Registration and Listing, Adverse Event Reporting. This is so because FDA has not taken the position that an IRC that is just extending the lives of the EndoWrist instruments meets the definition of "remanufacturer," as defined in 21 CFR § 820.3(w). Nor is it obvious that IRCs (or hospitals) that do not intend to resell repaired or refurbished EndoWrists are placing those devices "in commercial distribution," as defined in 21 CFR § 807.3(b). In my opinion, this is the correct approach to the enforcement of this regulation for two reasons:

(a) The original EndoWrist instrument was cleared as a *reusable* medical device (as opposed to a single-use device, the only other category of medical device defined by FDA), and the servicing or refurbishing does not change the intended use of the device (because it remains a reusable medical device), nor does it significantly change the safety or performance specifications of the EndoWrists; and

(b) When IRCs perform servicing or refurbishing activities for a hospital, without taking ownership or becoming involved in the sale or resale of such serviced or refurbished device, their activities do not meet the regulatory threshold of an entity placing a medical device into interstate commerce for commercial distribution.

9. FDA's classification of Iconocare's K210478 as "remanufacturing" does not demonstrate that all IRCs performing servicing or refurbishing of Intuitive's EndoWrists require a 510(k) submission and clearance, nor does FDA's decision to grant Iconocare's 510(k) application.

IV. FOREMAN'S OPINIONS CANNOT BE RECONCILED WITH FDA'S TREATMENT OF THIRD-PARTY ENDOWRIST REPAIR

10. In her report, Christy Foreman opines that "FDA communicated to certain third

parties that their activities constituted remanufacturing."[12] That position cannot be squared with a) the correspondence Foreman cites as evidence for her position, or b) FDA's embrace of the ongoing lack of clarity between servicing—which is not subject to the 510(k) clearance requirement—and remanufacturing.

A. Informal email correspondence between FDA and Rebotix makes clear that FDA has not required reusable medical device repair companies to seek 510(k) clearance.

11. As recently as July 22, 2022, FDA officials made clear that "FDA has not conducted an official regulatory evaluation" as to whether IRCs (such as Rebotix) are required to apply for 510(k) clearance to perform repairs on, and extend the number of lives for, EndoWrists.[13]

12. Although Foreman emphasizes prior informal correspondence from that same FDA employee in an effort to suggest that the agency had, in fact, made such a decision,[14] FDA most recently disclaimed that very correspondence by emphasizing that "[i]nformal communications with FDA staff *do not represent the formal position of FDA and do not bind or otherwise obligate or commit the agency to the views expressed*."[15] For this reason, when Rebotix indicated it wished to appeal what Foreman now describes as FDA's "position that a 510(k) was needed,"[16] FDA responded that, since FDA had made no such decision, "there is nothing for Rebotix to appeal at this time."[17] FDA left little doubt, in other words, that there was no agency decision as to the 510(k) clearance requirement to appeal.

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[12] Foreman Report at ¶ 16(c).
[13] *See* REBOTIX-175839.
[14] *See* Foreman Report ¶¶ 228–29.
[15] REBOTIX-175839, at -839 (emphasis added). This disclaimer is hardly novel—indeed, for much of my time with FDA my email signature block included a disclaimer to the same effect.
[16] Foreman Report ¶ 231.
[17] REBOTIX-175839, at -839.

13. That clear FDA statement that there is no agency regulatory determination to appeal undermines Foreman's conclusion that this correspondence "indicates that FDA ha[s] not deviated from its position that a 510(k) was needed,"[18] a conclusion that does not withstand even a cursory read of the relevant correspondence. Of course, if FDA, or even the FDA employee sending the email, had "not deviated from its position that a 510(k) was needed," they could and would have just said that in the email. Instead, Dr. Anthony Lee of FDA stated:[19]

From: Lee, Anthony
To: Rick Lyon; Chris G; Glenn P
Cc: Bittleman, Katelyn
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126
Date: Friday, July 22, 2022 7:20:23 AM
Attachments: image001.png

Dear Rebotix team,

In my prior communications below, specifically in my email dated Wednesday, April 06, 2022 5:58 AM in reference to CPT2000126, I used the term "decision" in a manner that may have incorrectly implied that FDA had made an official regulatory determination related to Rebotix, which Rebotix has now suggested it wants to "appeal." To clarify, FDA conducted a preliminary **informal assessment** of the limited materials previously provided by Rebotix, and FDA has not conducted an official regulatory evaluation.

14. Indeed, when an owner of Rebotix, Stan Hamilton, was asked how this email impacted his understanding of his previous correspondence with FDA—the very correspondence on which Foreman relies upon—Hamilton, who had participated in a meeting with FDA that preceded this email, explained that this email "negate[d] anything that they were appearing to do with respect to a regulatory determination or regulatory enforcement, and that was made clear in the last meeting that . . . included some fairly high people in the FDA. And it was clear that the walk back was occurring and that only an informal assessment was made."[20]

[18] Foreman Report ¶ 231.
[19] REBOTIX-175839, at -839.
[20] *See* Stan Hamilton Dep. (Nov. 4, 2022) Tr. at 99:5–100:3.

B. FDA's public statements confirm that the agency has not required reusable medical device companies to seek 510(k) clearance.

15. That FDA has not required 510(k) clearance for serviced EndoWrists or other laparoscopic surgical instruments reflects the reality that FDA has not yet issued its promised rulemaking on this topic, nor has FDA issued final guidance on "remanufacturing,"[21] in stark contrast to the agency's guidance documents for manufacturers regarding when a change to a medical device requires 510(k)[22] clearance.

16. In public statements in recent years, FDA has repeatedly reiterated the lack of clarity—and the need for further agency deliberation—regarding the kinds of activities that would constitute remanufacturing versus servicing in the context of medical device repair.

1. *2018 FDA White Paper & Public Workshop*

17. In 2018, FDA published a discussion white paper titled "Evaluating Whether Activities are Servicing or Remanufacturing" that acknowledged the lack of clarity between "servicing" and "remanufacturing" activities and attempted to lay out possible methods of resolving the confusion.

18. That white paper emphasized that "FDA makes an important distinction between these two activities; which of these two categories an activity falls within may determine the

[21] FDA's "Draft - Not for Implementation" states, "This draft guidance is intended to help clarify whether activities performed on devices are likely "remanufacturing." Such clarification is intended to help provide consistency and better understanding of applicable statutory and regulatory requirements." FDA, *Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff* (June 2021).

[22] FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff* (Oct. 2017).

applicability and enforcement of regulatory requirements such as those regarding quality systems, premarket notification, adverse event reporting, and registration and listing."[23]

19. FDA published that white paper for a public workshop on the distinctions between medical device servicing and remanufacturing. As one observer observed:

> Availability of device specifications and documentation is still the most contentious issue. As expected, OEMs and ISOs [Independent Service Organizations] have opposite views on the types and amount of device documentation that should be available to third party servicers. OEMs are primarily concerned with protecting their intellectual property, including device know-how and trade secrets, disclosure of which would mean forfeiture of proprietary knowledge and technology and key business advantages. ISOs argue that they need the technical specifications of devices to determine whether an activity would significantly change the safety or performance specifications of a device, and thus constitute remanufacturing. *FDA appears split on this issue because it respects the IP interests of the OEMs while acknowledging that it would be difficult for ISOs to accurately differentiate between servicing and remanufacturing without some information on device specifications*.[24]

20. That observer further noted the general consensus among the workshop's participants that substantial ambiguity remained as to what constitutes remanufacturing:

> FDA's flowchart to help differentiate servicing from remanufacturing *needs much more detailed decision points*. One of the main sessions of the workshop's first day involved in-depth discussion and application of FDA's proposed flowchart. During the session, breakout groups attempted to use the flowchart to determine whether the examples presented in FDA's White Paper represented servicing or remanufacturing. *Many breakout groups had long discussions about how to apply the flowchart, which was partly due to the vagueness of the examples and partly to the basic nature of the flowchart.* FDA's flowchart only has three categories of device changes—changes to components/parts/materials that contact body tissues or fluids, changes to dimensional or performance

[23] FDA, *White Paper: Evaluating Whether Activities are Servicing or Remanufacturing* (May 2018).

[24] Benjamin M. Zegarelli, *Observations from FDA's Public Workshop on Medical Device Servicing and Remanufacturing*, Nat'l Law Review (Dec. 19, 2018) (emphasis added).

> specifications of a component/part/material, and changes that introduce new or increased risk or modify performance or safety specifications—and in each case asks if the change significantly affects device performance or safety. *As proposed, the flowchart leaves too much room for interpretation*.[25]

2. *2021 Draft Guidance*

21. In June 2021, FDA confirmed that there still is confusion and lack of clarity regarding the distinction between "servicing" and "remanufacturing" when it published the draft guidance, "Remanufacturing of Medical Devices" for public comment.[26] FDA's own website states: "Many devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. *However, there is a lack of clarity regarding the distinction between 'servicing' and 'remanufacturing' of a device.* Most notably, remanufacturing has implications for the regulatory responsibilities of entities performing these activities."[27]

22. FDA made these statements as part of draft guidance that, tellingly, has never been finalized—further evidence that FDA has not defined the contours of "remanufacturing activity," and reinforcing the reality that FDA has not made any determinations with respect to any one particular type of reusable medical device, let alone EndoWrists specifically.

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[25] *Id.* (emphasis added).
[26] FDA, *Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff* (June 2021).
[27] FDA, *Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff* (June 2021), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices (emphasis added).

C. FDA's decision not to regulate third-party "service" activities as remanufacturing reflects a concerted effort to keep healthcare costs down.

23. FDA understands that requiring all non-OEM entities, including IRCs, third-party servicers, and healthcare servicing/biomedical engineering departments, to register as manufacturers or remanufacturers and abide by relevant regulations would substantially increase the cost to hospitals (and, ultimately, to patients) of using reusable devices. And so, in spite of enormous pressure from OEM lobbying and OEM trade groups, FDA has steadfastly refused to subject those service providers to remanufacturing requirements.

24. Importantly, Congress has not spoken clearly to this situation (as it has with single-use devices),[28] and so FDA has preserved the status quo. This is largely because FDA, in my opinion, does not see the public health case for subjecting non-OEM service providers to heightened regulatory requirements, making the inevitable increase in healthcare costs of doing so unjustifiable.

25. As it stands, there's substantial ambiguity as to which service providers might fall into the remanufacturing category (rather than servicing), which is why FDA first proposed a rulemaking on the topic. That this rulemaking has never been finalized only underscores the agency's cautious approach to the regulation of the servicing of reusable instruments. Intuitive's litigating position in this case ignores that FDA has carefully (and deliberately) elected to exercise caution in this area, particularly in the absence of an explicit legislative directive.

D. Foreman misconstrues FDA's public statements to reach an incorrect and contrary conclusion.

26. Ignoring all of this, Foreman's report postulates, "[o]bjective and publicly available evidence demonstrates that FDA has determined that removing or extending the usage

[28] *See infra*, Section VI.

limitation on EndoWrist instruments is a manufacturing activity, and as such, it requires 510(k) clearance."[29]

27. I see no such demonstration by FDA, and at any rate, I disagree that any particular "manufacturing activity" and "remanufacturing activity" can be equated in this way. Indeed, whether an entity is engaged in servicing, reprocessing, or refurbishing—as opposed to remanufacturing—determines whether the entity may be subject to 510(k) requirements—not whether that conduct qualifies as "manufacturing activity."[30]

28. As discussed, the lack of a clear distinction between these activities (except in the case of changing the intended use of a single-use device ("SUD") to be a reusable device, (noted below)) makes it subjective at best as to what constitutes a "significant change." It is an area that FDA, OEMs and third party organizations continue to struggle with and have not resolved, in part due to competitive issues,[31] as well as a variety of other concerns, including: economic, political, intellectual property, environmental, etc. See, for example, the ongoing debate[32] related to the reprocessing of SUDs, where entities that perform such activities have clearly been identified by FDA as remanufacturers (due to the change in the device's intended use) since the 2002 Medical Device User Fee and Modernization Act ("MDUFMA").

F. Foreman misreads FDA's response to Iconocare's 510(k) application.

29. Foreman attempts to erase FDA's pronouncement that it "has not conducted an official regulatory evaluation,"[33] by pointing to various instances in which FDA used a product

[29] Foreman Report, p. 47.
[30] FDA, *White Paper: Evaluating Whether Activities are Servicing or Remanufacturing* (May 2018).
[31] 61 Fed. Reg. 52609 - 52610 Preamble comment #28.
[32] Daniel Vukelich, *Good as new – reprocessing single-use devices* https://www.medicaldevice-developments.com/features/featuregood-as-new---reprocessing-single-use-devices-5663983/
[33] REBOTIX-175839, at -839.

code in response to Iconocare's 510(k) submission, which included the label "remanufacturing."[34] It is true that, in a largely ministerial action in September 2021, FDA added a product code "QSM" for remanufactured reusable surgical instruments as a result of the Iconocare 510(k) submission.

30. [redacted][35] This is a crucial distinction for purposes of understanding 510(k) clearance requirements, because it means that Iconocare unambiguously intended to "introduc[e]" repaired EndoWrists "into interstate commerce for commercial distribution," an independent requirement under FDA 510(k) regulation 21 CFR § 807.[36] As a result, the assignment of a "remanufacturing" product code to the instruments Iconocare intends to offer for sale does not mean that every hospital, healthcare facility, or IRC performing servicing, refurbishing, or reprocessing activities is subject to 510(k) clearance requirements, particularly where those entities do not intend to "introduc[e]" repaired devices "into interstate commerce for commercial distribution."[37]

31. In other words, even if FDA had implicitly announced that it considered IRCs that repaired, serviced, or refurbished EndoWrists to be remanufacturers through the assignment of a product code in response to Iconocare's 510(k) application—a highly unusual and highly unlikely means of declaring a drastic and consequential change in regulatory policy—those IRCs would not be required to seek 510(k) clearance, unless they *also* intended to place their repaired EndoWrists in "commercial distribution." The relevant regulations provide that "[c]ommercial

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[34] Foreman Report ¶ 232; *see also id.* ¶¶ 127–29, 133–34, 136.
[35] Restore-00112674, at -683 ([redacted]); *see also* Ferreira Dep. (Nov. 10, 2022) Tr. at 193:16-195:13.
[36] *See* 21 CFR § 807.81(a).
[37] *See* 21 CFR § 807.81(a).

distribution means any distribution of a device intended for human use which is held or offered for sale."[38] Although the exact interpretation of this regulation, much like the definition of "remanufacturer," remains subject to some ambiguity, it is my opinion that for reusable-device repair FDA would *not* consider a hospital that intended only to repair, service, or refurbish its own devices without selling them to another entity—or that contracted with an IRC to repair, service, or refurbish its EndoWrists—as having placed those devices "in commercial distribution."

32. At any rate, if FDA were inclined to announce a change in policy with respect to how it defines "remanufacturers," I would expect it do so through the one of the methods the agency has previously started (but not finished)—a formal rulemaking or the promulgation of a policy or guidance document(s), both processes in which all interested parties have the ability to participate and provide feedback.

33. Instead, FDA's decision to label Iconocare's product as a "remanufactured" device may well serve only to distinguish that product from the OEM EndoWrist; agency officials would not label that product as a "serviced" product, as such products by definition are not subject to 510(k) clearance. Indeed, product code including "remanufacturing" may have been the only option for FDA officials to use in order to distinguish the product from OEM EndoWrists. Accordingly, the Iconocare product codes do not clarify FDA's position on whether entities (including IRCs) that do not intend to sell or resell serviced or reprocessed devices nonetheless must seek 510(k) clearance.

[38] 21 CFR § 807.3(b). Note that this definition includes four exceptions, none of which is relevant here.

34. In addition, the fact that FDA granted Iconocare 510(k) clearance does not amount to a determination that such clearance is required—only that the cleared device is "substantially equivalent" to the predicate device (here, the EndoWrists). When Iconocare decided to seek 510(k) clearance for its own business purposes, the agency simply accepted Iconocare's position and reviewed it as it would any other 510(k) application.

V. FOREMAN FAILS TO RECONCILE INTUITIVE'S PRE-LITIGATION CONDUCT WITH ITS LITIGATING POSITION IN THIS CASE

35. Foreman fails to meaningfully grapple with Intuitive's demonstrated understanding of 510(k) requirements as applied to EndoWrists—an important omission, given that Intuitive's pre-litigation conduct is entirely inconsistent with its litigating position that 510(k) clearance is (and always has been) required to extend EndoWrist use limits.

36. Foreman maintains that "Intuitive's internal conduct does not contradict" its "assertion that third parties may not 'reset' the usage counter of EndoWrist instruments without 510(k) clearance."[39] In fact, Foreman barely addresses Intuitive's own treatment of that question, one of critical importance to the company.

A. Intuitive used Non-Filing Justifications to extend the number of uses for EndoWrists.

37. Foreman fails to mention, for example, that for at least some EndoWrists, Intuitive's 510(k) submission included performance testing for only 5 lives, and that Intuitive used a Non-Filing Justification (NFJ) to increase the number of lives to 10 before sending those EndoWrists to market.[40]

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[39] Foreman Report, ¶¶ 244–60.

[40] See Lowe Dep. (Nov. 3, 2022) Tr. at 30:4 – 9; *see also* Perry Dep. (Oct. 20, 2022) Tr. at 108:24 – 25 ("[T]he test reports that were initially in the 510(k) tested to 5 lives."); Intuitive-02038766, at -766 (Perry Dep. Ex. 82) ("We already went from 5 lives in the 510(k) to 10 lives when we started shipping on an NFJ.").

38. Intuitive marketed those 10-life EndoWrists for ***nearly a decade*** without submitting another 510(k) to bring them from 5 lives to 10. That approach, of course, reflects the reality that, where the applicability of the 510(k) clearance requirement is unclear, market participants tend to operate without such new clearance. But that approach is starkly at odds with Foreman's opinion that "removing or extending the usage limitation on EndoWrist instruments is a remanufacturing activity, and as such, it requires 510(k) clearance."[41]

39. At deposition, Foreman tried to reconcile her position with Intuitive's conduct by declaring that Intuitive's interpretation of the relevant regulations had been "an incorrect determination."[42] Foreman went even further when asked whether it was "unlawful for Intuitive to market ten-life Xi EndoWrists for the eight years when it had received 510(k) clearance for only five lives," by responding, "Well, technically speaking, any device that is not in compliance with its 510(k) would be considered out of compliance, which would be unlawful."[43]

40. This is a startling admission. Intuitive, according to its own expert, was operating unlawfully for eight years with respect to the very core of its business model—an area in which one would expect Intuitive to operate with substantial caution and care. That Foreman felt required to label Intuitive's years-long approach as "incorrect" and even "unlawful" to defend her own interpretation of the relevant regulations only underscores the fact that it is, at a minimum, unclear whether 510(k) clearance is required to extend the number of lives on EndoWrists.

[41] Foreman Report, p. 47.
[42] Foreman Dep. (Feb. 17, 2023) Tr. at 85:1–3.
[43] *Id.* at 85:4–10.

B. In the context of its Extended-Use Program, Intuitive concluded 510(k) clearance was unnecessary to extend the number of uses for EndoWrists.

41. Foreman's report does at least address Intuitive's Extended-Use Program, but even then she waits to do so until the end of her report—asserting only that Intuitive reviewed "the existing guidance" and "concluded that a NFJ was appropriate and that a 510(k) submission was not necessary."[44] This conclusion, too, conflicts with Foreman's unequivocal opinion that "removing or extending the usage limitation on EndoWrist instruments is a significant change, and . . . requires 510(k) clearance."[45]

42. Foreman is correct, however, that through the Extended-Use Program Intuitive extended the number of permitted uses on multiple EndoWrists without filing a 510(k). The NFJs on which Intuitive relied each explained that "[e]xtending the number of lives does not involve any changes to the intended use(s) or instrument design" and concluded that because "[i]ncreasing the number of lives for the Vinci X/Xi instruments referenced above is not expected to significantly affect the safety or effectiveness of the instruments[,] . . . a new 510(k) is not needed to support the proposed increase in the number of instrument lives."[46]

43. Moreover, even *after* Intuitive determined that it should submit a 510(k) on its Extended-Use EndoWrists, Intuitive continued to market Extended-Use EndoWrists. And even *after* FDA communicated that its "official advice" was to "roll back" Extended-Use EndoWrists during the pendency of that 510(k) application, Intuitive continued to market them for additional

[44] Foreman Report ¶ 250.
[45] Foreman Report, p. 47.
[46] Intuitive-00552716 (NFJ for Needle Drivers); Intuitive-00552697 (NFJ for Bipolar Cautery Instruments); Intuitive-00552728 (NFJ for Forceps).

uses.[47] At deposition, Intuitive's most senior regulatory affairs officials testified that continuing to market these devices, even before FDA issued 510(k) clearance, was not lawful.[48]

44. Foreman does not maintain—nor could she—that the relevant regulations or guidance documents changed between August 2020, when Intuitive determined that extending the number of lives for EndoWrists did not require a 510(k), and December 2021, when Intuitive ultimately submitted a 510(k) for those instruments.

45. And yet, at various points, Intuitive determined that (1) a 510(k) was not required to market Extended-Use EndoWrists; (2) a 510(k) was required, but that marketing Extended-Use EndoWrists without one was nevertheless permissible under the governing regulations (at least for Intuitive); and (3) a 510(k) was required, and that marketing Extended-Use EndoWrists was *not* permissible under the governing regulations (for Intuitive's rivals).

46. Intuitive somehow maintains that *each* of these three inconsistent positions was appropriate and reasonable in light of FDA's guidance.[49] That position is entirely inconsistent with its argument that IRCs' attempts to enter the market without 510(k) clearance violated FDA regulations, given that Intuitive itself did not think a 510(k) was necessary for its own extension of uses for the EndoWrists per their own NFJs.

C. Foreman's attempt to explain Project Dragon is belied by the record.

47. Lastly, Foreman barely addresses Intuitive's Project Dragon—waiting until the last paragraph of her report to do so.[50] As explained in my opening report, Project Dragon

[47] Claiborne Dep. (Nov. 21, 2022) Tr. at 33:25 – 35:23.
[48] Lowe 30(b)(6) Dep. (Nov. 3, 2022) Tr. at 35:7–10; Claiborne Dep. (Nov. 21, 2022) Tr. at 36–41.
[49] Lowe Dep. (Nov. 3, 2022) Tr. at 35; Claiborne Dep. Tr. 29–30, 36–41.
[50] Foreman Report, ¶ 260.

involved Intuitive's efforts to "explore[] the possible reclamation of used da Vinci EndoWrist instruments," so that those instruments could be repaired and resold at a lower cost.[51] Notably, documents related to that initiative indicate that Intuitive *did not* think that 510(k) clearance would be required to implement this idea.[52] That position, of course, is inconsistent with its stance in this litigation that the servicing of EndoWrists requires 510(k) clearance.

48. Foreman attempts to explain away this inconsistency by claiming that "Project Dragon was abandoned once Intuitive determined that it was more expensive," and that "[t]here was no testing to evaluate whether the usage limits on S/Si instruments could in fact be safely extended."[53] But the expense associated with repairing EndoWrists has nothing to do with the relevant question here—whether doing so would trigger 510(k) clearance requirements. Instead, Intuitive's concerns about feasibility seemed more related to the Intuitive's lack of global facilities and mechanisms to collect and redistribute refurbished EndoWrists. And, contrary to Foreman's assertion that there was no testing done to determine the feasibility of EndoWrists refurbishing, Intuitive's Senior Director of Services, Innovation, and Production Management testified that, "[f]ollowing remanufacturing or refurbishment of components, *we did deem that it was likely feasible*."[54] While testing may not have been completed, there is evidence of testing performed.

49. That same Intuitive executive asserted that Intuitive "did not undertake a full validation and verification of refurbished or remanufactured instruments."[55] Whether Intuitive

[51] Trautman Opening Report ¶ 74.
[52] Intuitive-00423534 at -573-574 (noting, under U.S. regulatory requirements, "Clearance/ registration required: No.").
[53] Foreman Report ¶ 260.
[54] Bair Dep. Tr. 50–51 (emphasis added); *see also* Intuitive-00147379 ("Feasibility Update" on Project Dragon).
[55] *Id.*

completed the full testing necessary to secure 510(k) clearance, however, has little to do with whether an application for such clearance is required in the first instance.

50. Intuitive's own conduct, therefore, demonstrates—at a minimum—a lack of clarity as whether 510(k) clearance was required to refurbish and reset the EndoWrists use counter beyond the number of uses established in their original 510(k) applications. Indeed, Intuitive's long-standing interpretation of the relevant regulations was that it was not required to submit a new 510(k) because (according to Intuitive, and as seen in the NFJs) the extensions did not change the intended use or make a significant change to the performance or safety specifications of the medical device.

VI. THE RELEVANT REGULATIONS DO NOT REQUIRE 510(K) CLEARANCE

51. Regardless of the fact that FDA has yet to expressly state whether IRCs must acquire 510(k) clearance to service and reset EndoWrists, it is my opinion that FDA would conclude the relevant regulations do not require 510(k) clearance.

52. This is true, as described below, for two reasons. First, as Intuitive itself acknowledged in the NFJs it relied on for its Extended-Use Program, repairing an EndoWrist does not "significantly change [] the finished device's performance or safety specifications, or intended use." 21 CFR § 820.3(w). And second, servicing an EndoWrist (at least without purchasing and reselling the reset device to other consumers) does not require a transfer of ownership or a commercial sale of the EndoWrist in question.

A. Repairing an EndoWrist does not significantly change the device.

53. Manufacturers and remanufacturers are subject to FDA requirements, such as registration, listing, premarket notification, unique device identification, quality systems, adverse

event reporting, recalls, corrections and removals, etc. However, legal entities that do not fall into those definitions, such as providers of servicing, refurbishing, or reprocessing (as long as the intended use of the device has not been changed, *i.e.*, changing a SUD to a reusable device as expressly called out in 2002 MDUFMA), are not required to comply with FDA regulatory requirements, and will not be required to do so unless and until such rulemaking policies are established. In 1998, FDA revoked CPG 7124.28, which pertained to "reconditioners or rebuilders," as it was inconsistent with, the 1996 Quality system regulation rulemaking.

54. From 1998 through to the 2002 MDUFMA, which spurred FDA to institute the policy that changing a SUD to a reusable medical device was a change in intended use for any legal entity, including IRCs, hospital/healthcare facilities, etc., reprocessing SUDs was common and permissible. I personally accompanied an FDA investigator on an inspection of an IRC related to this policy to explore the prevalent practice. I was also involved in FDA discussions with John Hopkins Hospital Healthcare facilities about its practice of routinely reprocessing SUDs to reusable devices prior to 2002. The 2002 MDUFMA provisions spurred FDA's change in policy for SUDs, whereas FDA had previously allowed many IRCs and hospitals to reprocess SUDs, which clearly changed the cleared intended use of devices without any change in ownership or sale in interstate commerce.

55. Here, the original EndoWrist was cleared as a *reusable medical device* (as opposed to a SUD, the only two categories of medical devices defined by FDA), and the servicing or refurbishing of that device does not change its intended use by continuing to

maintain the EndoWrist as a reusable medical device. Indeed, Foreman makes no argument that "a third party who resets an EndoWrist's use counter" has changed that device's intended use.[56]

56. Although, to date, FDA has not established policies to clarify the difference between servicing and remanufacturing for reusable devices, this activity is best understood as servicing, rather than remanufacturing.

B. Servicing an EndoWrist does not require a change in ownership.

57. FDA premarket applications are not required for those third-party organizations that simply service a medical device for the owner of the device without taking ownership of the device or selling the "serviced" device into interstate commerce for commercial distribution.

58. As described above, FDA only requires a legal entity/company to obtain premarket approval (e.g., a 510(k) clearance) if the company holds or offers a device for sale. A company is required to submit a premarket notification only when the "device is being introduced into commercial distribution," or when the "device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution." 21 CFR § 807.81. And, again, 21 CFR § 807.3(b) defines "commercial distribution" as "distribution of a device intended for human use which is *held or offered for sale*."

59. Here, the IRCs, which a) service EndoWrists for hospitals without taking ownership of the EndoWrists, and b) are not involved in the sale or resale of the serviced or refurbished EndoWrists, do not meet the regulatory threshold of an entity placing a medical device into interstate commerce for commercial distribution. As a result, based on my

[56] Foreman Dep. (Feb. 17, 2023) Tr. 66:13–18 ("Q. In this case, is it your opinion that a third party who resets an EndoWrist's use counter has significantly changed that device's intended use? A. No, it is not my opinion that the intended use has changed.").

experience and my understanding of how FDA handles these issues, it is my opinion that FDA would not require 510(k) clearance.

60. Foreman tries to confuse the issue by arguing that "FDA regulatory requirements apply where the product has been introduced into interstate commerce."[57] It is true, in that under the FD&C Act, for FDA to have authority to regulate a given product, that product must travel in interstate commerce.[58] But it is likewise true that a product that is sufficiently involved in interstate commerce such that it is *subject to* the authority of FDA is not, for that reason alone, required to submit 510(k) clearance. It simply means that FDA has the authority to require such clearance if the relevant regulations cover that product or activity. Here, the relevant provision requires "introduction into interstate commerce *for commercial distribution*,"[59] where "commercial distribution" has its own definition ("any distribution of a device intended for human use which is held or offered for sale") separate and apart from the "interstate commerce" requirement.[60] In short, the "interstate commerce" requirement represents only the first portion of this two-step inquiry.

61. At deposition, Foreman repeatedly acknowledged this point, explaining that, "the *first* concept is, is there movement in interstate commerce. And *then you could ask after that*, is it held for sale or not."[61] Whether a product—such as a repaired EndoWrist—is involved in

[57] Foreman Report ¶ 192.
[58] 21 U.S.C. § 321(b); *see also* Foreman Dep. (Feb. 17, 2023) Tr. ("Q. So when you're talking about a complaint being written that includes the 'introduced into interstate commerce language,' are you referring to satisfying the jurisdictional component of the United States Government's ability to bring the case in the complaint? A. Correct. Yeah.").
[59] 21 CFR § 807.81(a).
[60] 21 CFR § 807.3(b).
[61] Foreman Dep. (Feb. 17, 2023) Tr. 117:13–15 (emphasis added); *see also id.* at 116:18–23 (same); *id.* at 118:21–119:2) (same).

interstate commerce, in other words, is a necessary, but not a sufficient, condition for the 510(k) clearance requirement to apply.

C. FDA's regulatory approval of EndoWrists is not contingent on a specific number of "limited uses" of those devices.

62. Foreman states that "EndoWrist instruments were cleared by FDA as limited use devices, and efforts to remove or extend the usage limitation by companies other than the original equipment manufacturer (OEM) constitute remanufacturing activities."[62]

63. I completely disagree with this overreaching conclusion. A search of FDA's website easily proves there is no definition or category for "limited use devices." The website discusses two general categories of "durable" medical devices: 1) single use and 2) reusable medical devices. Regarding reusable medical devices, FDA states:

> These devices are designed and labeled for multiple uses and are reprocessed by thorough cleaning followed by high-level disinfection or sterilization between patients. They are made of materials that can withstand repeated reprocessing, including manual brushing and the use of chemicals.[63]

64. Some examples of reusable medical devices are:

- Surgical instruments, such as clamps and forceps;
- Endoscopes, such as bronchoscopes, duodenoscopes, and colonoscopes, used to visualize areas inside the body;
- Accessories to endoscopes, such as graspers and scissors; and
- Laparoscopic surgery accessories, such as arthroscopic shavers.[64]

65. There is no mention of "limited use" medical devices, outside of what Intuitive chose to discuss and validate in its market applications. The fact that FDA does not limit the use

[62] Foreman Report ¶ 16(b).
[63] FDA, *What are Reusable Medical Devices* (Jan. 12, 2018), https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/what-are-reusable-medical-devices.
[64] *Id.*

of reusable medical devices is acknowledged by Intuitive employees in their depositions and emails.[65] In fact, FDA's 510(k) clearance information for K214095, dated August 15, 2022, specifically refers to Intuitive's endoscopic instruments as just "reusable" and not "limited use."[66]

66. Foreman relatedly asserts that "FDA cleared EndoWrist instruments as limited-use devices." Again, I disagree because FDA cleared the EndoWrist surgical instruments as reusable devices, as seen above. It was Intuitive that specified its own use limits in the 510(k) applications. Further, Intuitive's 510(k) application device description and intended use of the EndoWrist surgical instruments do not state the use limits.[67] What is more, as described above, Intuitive's own conduct demonstrates that it understood full well that the specific use limits it chose in its 510(k) applications were not a necessary part of receiving 510(k) clearance. Indeed, Intuitive set use limits at 5 in its original 510(k) application for its Xi instruments, only to immediately increase those use limits to 10 relying on Non-Filing Justifications.

67. If there were any doubt on this point, FDA granted 510(k) clearance to surgical instruments associated with another surgical robot, the Senhance, *without any mention of use limits*. Notably, the relevant Senhance, 510(k) clearance, K171120 (dated October 13, 2017), used Intuitive's Si instruments as predicate devices, and FDA concluded the Senhance instruments—which are reusable without any use limit—were "substantially equivalent" to those devices.[68] Were the "use limits" that Intuitive elected to impose on its own EndoWrists essential

[65] INT-00214231, at -231 (Mario Lowe email regarding use limits, from Bair deposition).
[66] FDA, K214095 (Aug. 15, 2022), https://www.accessdata.fda.gov/cdrh_docs/pdf21/K214095.pdf.
[67] Id.
[68] *See* Foreman Dep. (Feb. 17, 2023) (Ex. 307).

to 510(k) clearance, FDA would not have (and, indeed, *could not have*) granted 510(k) clearance to the reusable surgical instruments used with the Senhance surgical robot.

68. Foreman separately claims, "FDA has acknowledged the limited use nature of EndoWrist instruments in communications to third parties."[69] In my opinion, however, it is irrelevant what FDA staff might or might not say informally in conversations during the 510(k) interactive review process. FDA reviewers' informal and nonbinding discussions with third party servicers or reprocessors were exploring the business model, ownership, sale, interstate commerce issues, as well as many technical issues, including the number of uses and necessary data to prove safety and effectiveness. There have been no formal agency policies or guidance documents rendered a) regarding the reprocessing of "limited reusable devices," beyond the FDA guidance document addressing reprocessing of "reusable" devices in general,[70] or b) for Intuitive's EndoWrist surgical instruments.

69. This is particularly true given that FDA made clear in its correspondence with Rebotix that "[i]nformal communications with FDA staff do not represent the formal position of FDA and do not bind or otherwise obligate or commit the agency to the views expressed."[71]

D. Foreman's attempt to analogize to single-use devices is inappropriate.

[69] Foreman Report, p. 46.
[70] FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff, https://www.fda.gov/media/80265/download
[71] REBOTIX-175839, at -839.

70. Foreman argues that "Congress also reached the same conclusion for a similar industry and activity – reprocessing – and amended FDA's governing statute to define premarket requirements for the reprocessors of devices labeled for single use."[72]

71. However, in § 302 of the 2002 MDUFMA, Congress specifically provided clarity around "Reprocessed *Single-Use* Medical Devices," and provided new regulatory requirements *for reprocessed single-use devices*. It expressly did not address reprocessing of reusable devices, such as EndoWrists.

72. FDA quickly took regulatory promulgation steps to solidify these changes in regulatory expectations for reprocessing of SUDs, but in all cases excluded reprocessing of reusable devices: "Federal Register Notices. On April 30, 2003 and June 26, 2003, FDA published Federal Register notices identifying the critical reprocessed *single-use devices* whose prior exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). On April 13, 2004, FDA published a Federal Register notice identifying the semi-critical reprocessed single-use devices whose prior exemption from 510(k) is terminated, and for which validation data is now required in a 510(k)."[73]

73. Foreman's argument that the MDUFMA provisions and its resulting regulations should be applied to reusable devices seems entirely wrong, having personally been involved in some of the agency discussions, as well as the GMP Advisory Committee discussions on this matter. Congress could have included reusable devices in MDUFMA, but did not, in part because the agency had asked the OEM industry for evidence of safety or performance problems

[72] Foreman Report, p. 51.
[73] FDA, *Summary of the Medical Device User Fee and Modernization Act of 2002* (July 8, 2019), https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/summary-medical-device-user-fee-and-modernization-act-2002#4.

related to the reusable device reprocessing, and the OEM industry had only produced anecdotal stories similar to testimony also seen more recently in 2018. In the 20 years since the passing of this legislation, FDA has not issued any positions stating that reusable devices should now be included, for example, in Medical Device User Fee Amendments 2022 (MDUFA V).[74] It appears from FDA's inaction on this issue that the agency is unwilling to move without statutory authority. To me, this suggests that FDA has rejected the application that Foreman espouses.

74. There is good reason, moreover, to treat reprocessing single-use and reusable devices differently in the context of medical device servicing or refurbishing. Reprocessing a SUD to enable further uses effectively converts that device into a reusable device, quite clearly changing the intended use of that instrument. As a result, the reprocessing of SUDs plainly constitutes a remanufacturing activity. Further, as already discussed above, Congress's 2022 amendments spurred FDA to overcome the conflict by requiring a 510(k) for reprocessing SUDs where a 510(k) is required for "commercial distribution" when the device is "held or offered for sale."[75]

75. But even so, it is important to note that FDA did not regulate servicing, refurbishing, or reprocessing of SUDs as remanufacturing activity, until Congress passed the MFUFMA provisions, a reflection of the agency's considered hesitation to overregulate an area that is crucial to the healthcare industry's efforts to keep costs down.

76. Simply extending the number of uses on a reusable device, like an EndoWrist, does not change the intended use in any meaningful way – even according to Intuitive's own

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[74] FDA, *Medical Device User Fee Amendments 2022* (Jan. 18, 2023), https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2022-mdufa-v.

[75] 21 CFR § 807.3(b).

NFJs. Accordingly, the question of whether servicing, refurbishing, or reprocessing constitute remanufacturing activity is a substantially more difficult question. It is not surprising, in my opinion, that FDA has decided not to regulate such servicing, refurbishing, or reprocessing in all cases as remanufacturing, because 1) doing so would substantially increase healthcare costs, and 2) there is no clear Congressional directive that such regulation is necessary.

VII. GIVEN THE LACK OF REGULATORY CLARITY, THE THREAT OF FDA ENFORCEMENT WOULD NOT HAVE DETERRED ENTRANTS INTO THE MARKET FOR ENDOWRIST SERVICING, REFURBISHING, OR REPROCESSING.

77. Intuitive's own conduct demonstrates the lack of clarity on this regulatory topic. Indeed, Intuitive first spoke to FDA about its 510(k) application—and how to handle marketing of Extended-Use EndoWrists—on December 23, 2021, just four days before it ultimately submitted that application.[76] There is no evidence that Intuitive had any plans to take Extended-Use EndoWrists off the market during the pendency of its 510(k) application, indicating that Intuitive expected that marketing those instruments would not trigger enforcement activity from FDA.

78. That expectation tracks Foreman's own "experience," in which "FDA does not take enforcement action against a company who is actively making an effort to bring a product into regulatory compliance after being informed of a non-compliance."[77] At deposition, Foreman further elaborated on this point, explaining that FDA sometimes chooses to exercise "enforcement discretion" in certain situations in which it could assert its regulatory authority:

> Enforcement discretion is a tool that FDA can use, and -- and they will use frequently when the circumstances are appropriate, when there is a potential

[76] Claiborne Dep. (Nov. 21, 2022) Tr. at 29.
[77] Foreman Report ¶ 252 n.194.

regulatory requirement in place and they are choosing not to enforce requirements.[78]

79. It is important to note that true "enforcement discretion" is effectively not an official agency position unless it is published and thus is applied across the board for that set of circumstance for all companies involved in such activities. When FDA chooses not to prosecute an individual company for a particular legal violation – a more precise term for that decision is "prosecution discretion," as compared to how FDA utilizes published "enforcement discretion," such as its "enforcement discretion" not to regulate general health applications.[79]

80. As a result, and in light of the substantial lack of clarity on this regulatory issue, IRCs could and would continue to service, refurbish, reprocess and reset EndoWrists and simply work with FDA to satisfy any concerns it might raise until an official published FDA policy terminates the prior exemptions from 1998, as was done for SUDs back in the early 2000s.

VIII. CONCLUSIONS

81. As stated in my original report, because FDA's long-promised rulemaking (to clarify which specific activities by servicers or refurbishers, if any, are in fact regulated by FDA) still has not been promulgated, it is my opinion that IRCs or third-party servicers, refurbishers, or reprocessors have not been subject to FDA regulations since 1998. Specifically, I believe that, based on FDA's approach in this area, FDA would not require 510(k) clearance for an IRC (that is not a reseller) to extend the lives of EndoWrist instruments, nor would FDA require

[78] Foreman Dep. (Feb. 17, 2023) Tr. 76:20–77:4.
[79] *See* FDA, *Device Software Functions Including Mobile Medical Applications*, https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications; *see also* FDA, *Policy for Device Software Functions and Mobile Medical Applications*, https://www.fda.gov/media/80958/download

compliance with the Quality System regulation 21 CFR § 820 or other FDA regulations, such as Registration and Listing, Adverse Event Reporting. This is so because FDA has not taken the position that an IRC that is just extending the lives of the EndoWrist instruments meets the definition of "remanufacturer," as defined in 21 CFR § 820.3(w). Nor is it obvious that IRCs (or hospitals) that do not intend to resell repaired or refurbished EndoWrists are placing those devices "in commercial distribution," as defined in 21 CFR § 807.3(b). In my opinion, this is the correct approach to the enforcement of this regulation for two reasons:

(a) The original EndoWrist instrument was cleared as a reusable medical device (as opposed to a single-use device, the only other category of medical devices defined by FDA), and the servicing or refurbishing does not change the intended use of the device by continuing to maintain the EndoWrist instrument as a reusable medical device; and

(b) The servicing or refurbishing activities, such as those performed by IRCs, do not constitute a significant change to the finished device's performance or safety specifications, as confirmed by: i) Intuitive's own documents and NFJs; as well as ii) the FDA's current stance as of July 2022, in *not* articulating to Rebotix that its activities are "remanufacturing."

(c) IRCs and hospitals or healthcare facilities, that do not choose to place reprocessed usable medical devices into commercial distribution for sale, do not meet the requirements under 21 CFR § 807 related to the regulatory requirements for a 510(k) cleared application.

82. Thus, in my opinion, there is not now and there has not been any regulatory bar for IRCs servicing EndoWrists, nor any set of specific requirements for them to do so. Nor will there be any such bar or requirements unless and until an FDA rule, policy, or guidance

document outlining a new policy to the contrary is published in the Federal Register and made effective. Given this reality, IRCs could and would continue to service or refurbish EndoWrists for hospital clients were such entities willing to hire them to do so.

Kimberly A. Trautman — March 1, 2023

Kimberly A. Trautman — Date

Exhibit A

EXHIBIT A

***Note*: This list is in addition to the materials included in Exhibit B of my Opening Report.**

Depositions

In re: Da Vinci Surgical Robot Antitrust Litigation, No. 3:21-cv-03825-VC

- Deposition and Exhibits of Stan Hamilton, November 4, 2022
- Deposition and Exhibits of Christy Foreman, February 17, 2023
- Deposition and Exhibits of Ted Claiborne, November 21, 2022
- Deposition and Exhibits of Rick Ferreira, November 10, 2022

Other Expert Reports

In re: Da Vinci Surgical Robot Antitrust Litigation, No. 3:21-cv-03825-VC

- Expert Report of Christy Foreman, January 18, 2023
- Expert Report of Kimberly A. Trautman, December 1, 2022

Bates-Stamped Materials

REBOTIX-175839

Restore-00112674

Intuitive-02038766

INT-00214231

INT-00147379

Third Party Materials

Academic Literature

- C.F.R. § 807.81
- 21 C.F.R. § 807.3
- Benjamin M. Zegarelli, *Observations from FDA's Public Workshop on Medical Device Servicing and Remanufacturing*, Nat'l Law Review (Dec. 19, 2018)

- 21 U.S.C. § 321

Publicly Available Data

- https://www.fda.gov/media/150141/download
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessingmedical-devices-health-care-settings-validation-methods-and-labeling
- https://www.medicaldevice-developments.com/features/featuregood-as-new---reprocessing-single-use-devices-5663983/
- https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/what-are-reusable-medical-devices
- https://www.fda.gov/media/80265/download
- https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2022-mdufa-v
- https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications
- https://www.fda.gov/media/80958/download
- TransEnterix, Inc. Fact Sheet: Senhance Surgical System Highlights
- TransEnterix K171120 dated October 13, 2017
- TransEnterix K180163 dated May 25, 2018
- TransEnterix K181517 dated October 9, 2018
- TransEnterix K183098 dated December 6, 2018
- TransEnterix K192877 dated November 22, 2019